1652

Docket No.: 28341/00233.NCP
(PATENT)

#8
B.G.J
11/12/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Kletzien et al.

Application No.: 09/851,873 Group Art Unit: 1652

Filed: May 8, 2001 Examiner: R. Hutson

For: Human Caspase-12 Materials and Methods

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

This paper is being timely filed in response to the office action mailed September 25, 2002. Applicants provisionally elect the claims of Group I, which are believed to be claims 1-8, with traverse. Applicants further provisionally elect sequence group R, SEQ ID NO:76 or a sequence encoding SEQ ID NO:79, with traverse.

Applicants request that the restriction requirement be reconsidered because the Examiner has not shown that a serious burden would be required to examine the claims of Groups I-VIII. M.P.E.P. § 803 provides:

> If the search and examination of an application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added.*)

Thus, for a restriction to be proper, the Examiner must satisfy the following two criteria: (1) that independent and distinct inventions are being claimed (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. *See* M.P.E.P. § 803.

The Examiner imposed a 27-way restriction requirement among Groups A-A' of polynucleotide sequences recited in the pending claims. In support, the Examiner asserted

that the sequences were unrelated and cited M.P.E.P. §§ 806.04 and 808.01. The cited sections of the M.P.E.P. provide support for restricting independent inventions, such as a shoe and a locomotive bearing, or a process of painting a house and a process of boring a well (*see* M.P.E.P. § 806.04).

> "The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatusincapable of being used in practicing the process." (M.P.E.P. § 802.01.)

In the present case, the Examiner imposed a restriction among sequences of polynucleotides (Groups A-U) and polypeptides (Groups V-A'). The polynucleotides of Groups A-U are isoforms of human caspase-12 (specification at page 5, lines 6-9 and 18-23 and at page 5, line 28 to page 6, line 9); the polypeptides of Groups V-A' are peptides of human Caspase-12 (specification at page 5, lines 4-6). Thus, the specification as filed disclosed the relationship among these molecules. Further, the molecules are connected in design (polynucleotides encoding a Caspase-12 polypeptide or a Caspase-12 peptide), operation (polynucleotides produce the encoded Caspase-12 polypeptide by expression, a process known in the art; peptides operate by exhibiting an activity of Caspase-12), and effect (production of the encoded Caspase-12 polypeptide or activity of Caspase-12).

The Examiner concluded that "where structural identity is required, such as for hybridization or expression, the different sequences have different effect." (Office Action at page 4.) Applicants respectfully submit that the Examiner's premise, that "structural identity is required" for hybridization or expression, is flawed. "Structural identity" is not required for hybridization or expression. For example, claim 14 is drawn to polynucleotides that hybridize under highly stringent hybridization conditions and these conditions are defined at page 6, line 29 to page 7, line 11 of the specification. Immediately following a recitation of the conditions, applicants indicated that polynucleotides encoding human allelic variants were preferred. Polynucleotides that encode variants do not even encode a polypeptide of the same sequence and are clearly not identical in sequence themselves. Analogously, there is no requirement that expression of polynucleotides imposes a requirement of identical sequences on either the polynucleotides or the encoded polypeptides. As established above, such

polynucleotides and polypeptides, like all of the polynucleotides and polypeptides of the instant claims, have not been shown to have different effects. There can be no question that such products have not been shown to be independent inventions, such as a shoe and a locomotive bearing (*see* M.P.E.P. § 806.04). Accordingly, the restriction is improper and should be withdrawn.

Applicants also note that the claims reciting the subject matters of Groups A-A' are Markush-style claims (*see, e.g.,* claim 9, depending from claim 4, and claim 13). Guidance in restriction practice involving Markush-style claims is found in M.P.E.P. § 803.02, which provides that "it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." As noted in the preceding paragraph, the specification repeatedly discloses that the polynucleotides generally encode a Caspase-12 peptide and the polypeptides exhibit a Caspase-12 activity, establishing the unifying principle of the invention. Accordingly, the restriction is improper and should be withdrawn.

Applicants also submit that the Examiner has not established (1) that the claims of Groups I-VIII are drawn to independent and distinct inventions, and (2) that is would present a serious burden to examine these claims together. The Examiner stated that Groups I-III are unrelated, relying on M.P.E.P. §§ 806.04 and 808.01. Section 806.04, addresses independent inventions, such as different combinations, and provides the examples of a shoe and a locomotive bearing, or processes of painting a house and boring a well. Section 808.01, addressing independent inventions and citing to M.P.E.P. § 806.04, states that "[t]his situation, except for species, is but rarely presented, since persons will seldom file an application containing disclosures of independent things." The Examiner has not asserted that the claims categorized in Groups I-VIII are drawn to species of some genus, and that "rare situation" is not presented here. The polypeptides of Group I may be produced using the polynucleotides of Group II and those polypeptides may be used to elicit the antibodies of Group III. The antibodies of Group III specifically bind the polypeptides of Group I and, in certain embodiments, may identify the polynucleotides of Group II. Accordingly, these groups of claims are related. Therefore, restriction among Groups I, II and III is improper and should be withdrawn.

The Examiner further asserted that Group I and Groups IV, V, and VI are related as product and processes of use, but the Group I polypeptides can be used in the materially different process of synthesizing antibodies. Applicants submit that the process of synthesizing antibodies is not materially different from the processes of claims of Groups IV-VI because the antibodies can be used in those processes as controls and can be identified as candidate inhibitors themselves in such processes. The process of using a polypeptide to synthesize an antibody or to identify candidate inhibitors (e.g., such antibodies) of that polypeptide is not analogous to the unrelated and independent processes of painting a house or boring a well exemplified in M.P.E.P. § 806.04. Accordingly, restriction between Group I and Groups IV, V, and VI is improper and should be withdrawn.

The Office Action supports restriction between Groups II and III, on the one hand, and Groups IV-VII on the other, by asserting that neither the polynucleotides (Group II) or antibodies (Group III) are used or made by the methods of Groups IV-VII. Applicants disagree and note that the polynucleotides of Group II may be used to produce the polypeptides used in the methods of Groups IV-VII; analogously, the antibodies of Group III may be subjected to the screening methods of Groups IV and V as they are potential inhibitors, and those same antibodies may be used in the treatment methods of Groups VI and VII. Again, the subject matters of these groups of claims bears no relation to the types of unrelated subject matters exemplified in the M.P.E.P. and the claims of Groups II, III, and IV-VII are related. Accordingly, the restriction is improper and should be withdrawn.

The Office Action also restricts claims of Groups I (polypeptides) and VI (treatment methods using caspase-12 inhibitors). Applicants traverse and note that the polypeptides are used to identify the inhibitors used in treatment. Claim 40 of Group VI, depending from 38, is informative. Claim 38 is drawn to a method of identifying a candidate inhibitor of binding of human caspase-12 by contacting a test compound and a polypeptide of Group I. Thus, the subject matters of the claims of Groups I and VI are not unrelated and independent in the sense contemplated by the M.P.E.P.; a polypeptide and a treating method using an inhibitor of such a polypeptide are not analogous to house painting and well boring. The restriction is improper and should be withdrawn.

With respect to the restriction imposed between Groups II and VIII, Applicants submit that a process of using a polynucleotide of Group II in a hybridization method is not a materially different process from a method of delivering the polynucleotide to a subject. The hybridization method is essentially a method to identify polynucleotides of like structure, i.e., a form of self-authentication. On this theory, any product could be used in a method designed to confirm its identity and that method would be materially different from any patentable utility that product might exhibit. Thus, a hybridization method, which is arguably a method of self-identification, is not materially different from a method of delivering the polynucleotide to a subject. Accordingly, the restriction is improper and should be withdrawn.

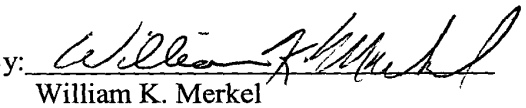
The restriction among Groups I and III, on the one hand, and Group VIII on the other, is also traversed. Applicants disagree that the polypeptides of Group I and the antibodies of Group III cannot be used or made by the method of Group VIII. Delivering the polynucleotide (Group II) to a subject may result in expression of the polypeptide of Group I and such expression may be directly involved in achieving a therapeutic benefit; analogously, delivery of the polypeptide-encoding polynucleotide of Group II to a subject may be designed to facilitate polypeptide expression resulting in neutralization of antibody in that subject. Accordingly, the products of Groups I and III are not unrelated to the delivery method of Group VIII. The restriction is improper and should be withdrawn.

The Examiner also imposed a restriction among Groups V-VIII, asserting that the methods comprise different steps, utilize different products and produce different results. In response, Applicants traverse. The candidate inhibitors identified using the method of Group V may be used in the treatment methods of either of Groups VI or VII; the method of delivering a polynucleotide to a subject (Group VIII) may also be used in the methods of Groups VI or VII. In addition, the polynucleotide delivery of Group VIII may be used to express (i.e., produce) the polypeptide used in the method of identifying candidate inhibitors of Group V. As established above, the claims that have been categorized in Groups V-VIII are related. Accordingly, the restriction is improper and should be withdrawn.

For the foregoing reasons, reconsideration and modification or withdrawal of the restriction requirement is requested. It is submitted that all claims are now in condition for allowance and Applicants respectfully request an early notification thereof.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN
Attorneys for Applicants
6300 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606-6357
(312) 474-6300

By: 
William K. Merkel
Reg. No. 40,725

October 25, 2002